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| APPLICATION NO.                            | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. 3592 |  |
|--|-------------|----------------------|-------------------------|-----------------------|--|
| 10/056,511                                 | 01/31/2002  | Nora B. Aghassi      | P-6335.02(CONT)         |                       |  |
| 7590 03/11/2004                            |             |                      | EXAMINER                |                       |  |
| JACKSON W.                                 | * -         | LUDLOW, JAN M        |                         |                       |  |
| Suite 2100                                 |             |                      | ART UNIT                | PAPER NUMBER          |  |
| 112 E. Pecan<br>San Antonio, TX 78205-3731 |             |                      | 1743                    |                       |  |
| <b>5</b> , -                               |             |                      | DATE MAILED: 03/11/2004 |                       |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary   |  | Application | No.  | Applicant(s)   |                     |  |  |  |  |
|---|--|-------------|--|----------------|---------------------|--|--|--|--|
|   |  | 10/056,511  |  | AGHASSI ET AL. |                     |  |  |  |  |
|   |  | Examiner    |  | Art Unit       |                     |  |  |  |  |
| -   |  | Jan M. Ludl | l l  | 1743           |                     |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  |  |             |  |                |                     |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |  |             |  |                |                     |  |  |  |  |
| Status  |  |             |  |                |                     |  |  |  |  |
|   | Responsive to communication(s) filed on <u>11 December 2003</u> .  |             |  |                |                     |  |  |  |  |
| , —   | This action is <b>FINAL</b> . 2b) This action is non-final.  |             |  |                |                     |  |  |  |  |
| 3)  | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is  |             |  |                |                     |  |  |  |  |
|   | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  |             |  |                |                     |  |  |  |  |
| Disposition of Claims   |  |             |  |                |                     |  |  |  |  |
| 5)□<br>6)⊠<br>7)□   | 4)  Claim(s) 1-20 is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.  5)  Claim(s) is/are allowed.  6)  Claim(s) 1-20 is/are rejected.  7)  Claim(s) is/are objected to.  8)  Claim(s) are subject to restriction and/or election requirement. |             |  |                |                     |  |  |  |  |
| Application Papers  |  |             |  |                |                     |  |  |  |  |
| 9) The specification is objected to by the Examiner.  10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |  |             |  |                |                     |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |  |             |  |                |                     |  |  |  |  |
| Priority under 35 U.S.C. § 119  |  |             |  |                |                     |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.   |  |             |  |                |                     |  |  |  |  |
| 2) Notice 3) Infor  | nt(s) ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) er No(s)/Mail Date  | ,           | 4) Interview Summary Paper No(s)/Mail Do 5) Notice of Informal F 6) Other: | ate            | <sup>-</sup> O-152) |  |  |  |  |

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1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 1. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.
  - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103® and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 1-2, 4-6, 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brigati.

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Brigati teaches a block 250 for holding slides 10 separated from cover slides 30 by shim 22. Protuberances 146, 148 can be used to hold the cover slide, shim and slide in the block by friction fit, as claimed in, e.g., instant claim 4. The capillary space between the two slides 10, 30 constitutes the instant headspace and the bottom opening the instant injection port. An elastomeric film 64 has openings 66 to contain treatment fluid which is drawn into the headspace by capillarity (figure 3C). The slides and fluids can be contacted in an automated device at stations 13-16 as shown in figure 6. An absorbent can be provided at the end of the slide to remove fluids form the headspace (figure 3D).

Brigati fails to teach a "cassette" or housing surrounding the film and block.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a housing over the contacting stations in order to contain the reagents from outside contaminants, in order to protect technicians from vapors and/or leaks, and/or for other reasons for containing instrumentation as was known in the art at the time the invention was made. With respect to claims 6, 24, it would have been obvious to provide a "cap" or lid or other opening in order to provide access to the contents of the housing for repair, observation, etc. as was known in the art. With respect to the relief port, the gap between the two slides at the edge of the shim allows venting.

3. Claims 1-3, 5-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chianese.

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Chianese teaches a film 10 with reagent containers 22 in holders 20 attached to slide assembly 12 via inlet port 14. Outlet port 26 provides venting to waste. The slide assembly includes sample slide 30, cover slide 28 and spacer 32 defining head space 24. A roller 48, or rollers 66, 68 are provided to move the reagents from the containers to the slide assembly, but other compression means can be used, including a reciprocating platen (instant piston) (col. 4, lines 50-68 and col. 7, lines 1-25). The film can be straight or arcuate (bridge col. 2-3). With respect to claim 18, more than one reagent can be provided simultaneously to mix on contact (col. 5, lines 5-10). Thermal control can be provided (col. 6, line 12). Timing can be controlled by the length of the

Chianese fails to teach a "cassette" or housing surrounding the film and slide assembly.

strip or by microswitches to the roller motors (col. 7, lines 1, 51-52).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a housing over the film and slide assembly in order to contain the reagents from outside contaminants, in order to protect technicians from vapors and/or leaks, and/or for other reasons for containing instrumentation as was known in the art at the time the invention was made. With respect to claims 6, 24, it would have been obvious to provide a "cap" or lid or other opening in order to provide access to the contents of the housing for repair, observation, etc. as was known in the art. With respect to the claimed container structure and pressure exerting means, it would have been obvious to provide known alternate containers openable by pressure application and known alternate pressure application means in order to provide the

the art as indicated by Chianese at col. 1, line 64.

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containment and release functions taught by Chianese. With respect to claim 7, it would have been obvious to use alternate known joining means for clamping the slide assembly together. With respect to claim 20, it would have been obvious to provide an absorbent in the waste tank in order to draw and/or contain the liquid as was known in

2. Applicant's arguments filed December 11, 2003 have been fully considered but they are not persuasive.

Applicant argues that the method of delivery of Brigati differs from that of the instant invention. This argument is not persuasive because the instant claims are not directed to a method of delivery. Applicant argues that the film of Brigati differs in form and function from the instant film, but points to no claim language defining the difference in form and/or function. The film of Brigati comprises a container in that the surfaces of the film contain the fluid. Applicant argues that the instant cassette is more than a simple housing, but fails to point to any claim language defining over a housing. Applicant argues that the examiner has shown no evidence of the obviousness of a housing, but applicant has not argued that a housing would not be obvious for the reasons described by the examiner. Further, Brigati describes an automated apparatus for use with the slide device. In that Brigati teaches that Figure 6 shows the interior of the device (col. 11, line 49), it would have been obvious to provide an exterior structure or housing surrounding the interior. Applicant argues that the cap is not shown by the prior art, but does not argue the obviousness of providing a lid or cap for access to the interior of the automated apparatus of Brigati.

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Applicant argues that instant claim 1 differs from Chianese because the claim requires a moving strip and a fixed injection port. However, there is no language in claim 1 directed to such limitations. Similarly, there is no piston in claim 1 (and applicant has not addressed the teaching of a platen in Chianese), nor any limitation precluding connection of various capsules to a common passageway. There are no structural limitations to the injection port defining over the port of Chianese. Applicant argues that the method of use differs form the instant invention, but the instant claims are not directed to a method of use. Applicant argues that the instant cassette has more function than a mere housing, but fails to point to any limitation in the claims supporting this position. Applicant argues that the examiner has provided no evidence of teaching of a cassette or housing, but does not argue the obviousness of providing such a structure as argued by the examiner. The examiner notes, however, that Chianese shows a support 42 for the film (Fig. 5) and suggests a thermally controlled slide holder (col. 6, line 12) for automated processing, which taken together suggests a housing for the elements of the invention.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (571) 272-1260. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jan M. Ludlow Primary Examiner Art Unit 1743

Jml March 8, 2004